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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/719,272 05/04/01 YAMAMOTO H 19036/36959

HM12/0823

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EXAMINER

DAVIS, N

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

08/23/01

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/719,272

Applicant(s)

YAMAMOTO ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-20-01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19, 27, and 28, drawn to an antibody having specificity to LAR a hybridoma cell line that produces the antibody to LAR, and a method of making an antibody.

Group II, claim(s) 20-23, and 26, drawn to a method of quantitative determination of LAR.

Group III, claim(s) 24-26, drawn to a method of producing LAR.

Group IV, claim(s) 29-31, drawn to a method of diagnosis of thyroid carcinoma using the antibody to LAR.

Group V, claim(s) 32, drawn to a composition of histological diagnosis of thyroid carcinoma comprising the antibody to LAR.

Group VI, claim(s) 33-38, drawn to DDS formulation targeted to thyroid carcinoma using the antibody to LAR.

Group VII, claim(s) 39, drawn to a method of diagnosis by via measuring LAR expression.

2. The inventions have been found by the examiner to have no special technical feature that defined a contribution over the prior art because Schlessinger, (1992, WO 92/01050) teach LAR and antibodies with specificity to LAR. Since the inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single inventive concept and lack unity of invention.

3. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: The invention of Group I is drawn to an antibody specific for LAR, a hybridoma cell line that produces the LAR antibody, and a method of making a LAR antibody. The invention of Group II is drawn to determination of LAR. The invention of Group III is drawn to a method of producing LAR. The invention of Group IV is drawn to a method of diagnosis using the LAR antibody. The invention of Group VI is drawn to a composition comprising LAR. The invention of Group VII is drawn to a DDS formulation comprising the LAR antibody. The invention of Group VII is drawn to a method of measuring LAR expression.

4. The Inventions of Groups I, V, and VI (products) and II-IV and VII (methods) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I, V, and VI may be used for a number of different processes that are very much unrelated. For example, the LAR antibody of Group I may not only be used in the methods of Group IV and VII, but may also be used for immunopurification. Likewise, the method of Group IV may be practice using a different antibody.

5. The products of Groups I, V, and VI are drawn to structurally and functionally different molecules with different immunological properties, each invention requires different reagents and steps to make and characterize it.

6. The methods of Groups II-IV and VII relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.
August 20, 2001


GEEYHA P BANSAL
PRIMARY EXAMINER